The statutory authority for this rule is found at subsection 12-43.4-202(2)(b), C.R.S. The purpose of this rule is to provide necessary definitions of terms used throughout the rules. Defined terms are capitalized where they appear in the rules, to let the reader know to refer back to these definitions. When a term is used in a conventional sense, and not intended to be a defined term, it is not capitalized.

With regard to the definition of Child-Resistant, the State Licensing Authority relied extensively upon written commentary provided by a public health agency within a Colorado hospital, which had conducted a health impact assessment of packaging regulations, looking at accidental ingestion of medical marijuana. The assessment was supported by others in the public, including industry representatives and a physician specializing in medical toxicology.

With regard to the definition of Restricted Access Area, the State Licensing Authority relied extensively upon written commentary provided by a consumer advocate.

#### R 103 - Definitions

<u>Definitions</u>. The following definitions of terms, in addition to those set forth in section 12-43.4-103, C.R.S., shall apply to all rules promulgated pursuant to the Retail Code, unless the context requires otherwise:

"Advertising" means the act of providing consideration for the publication, dissemination, solicitation, or circulation, visual, oral, or written, to induce directly or indirectly any Person to patronize a particular a Retail Marijuana Establishment, or to purchase particular Retail Marijuana or a Retail Marijuana Product. "Advertising" includes marketing, but does not include packaging and labeling. "Advertising" proposes a commercial transaction or otherwise constitutes commercial speech.

"Alarm Installation Company" means a Person engaged in the business of selling, providing, maintaining, servicing, repairing, altering, replacing, moving or installing a Security Alarm System in a Licensed Premises.

"Applicant" means a Person that has submitted an application pursuant to these rules that was accepted by the Division for review but has not been approved or denied by the State Licensing Authority.

"Batch Number" means any distinct group of numbers, letters, or symbols, or any combination thereof, assigned by a Retail Marijuana Cultivation Facility or Retail Marijuana Products Manufacturer to a specific Harvest Batch or Production Batch of Retail Marijuana.

"Cannabinoid" means any of the chemical compounds that are the active principles of marijuana.

"Child-Resistant" means special packaging that is:

Designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly as defined by 16 C.F.R. 1700.20 (1995) and ASTM classification standard D3475-12, <a href="http://www.astm.org/Standards/D3475.htm">http://www.astm.org/Standards/D3475.htm</a>. Note that this rule does not include any later amendments or editions to the Code of Federal Regulations or the ASTM classification

standards. The Division has maintained a copy of the applicable federal regulation and ASTM classification standard, which are available to the public.

- b. Opaque so that the product cannot be seen from outside the packaging;
- Closable for any product intended for more than a single use or containing multiple servings, and
- d. Labeled properly as required by the R 1000 Series.

"Container" means the sealed package in which Retail Marijuana or a Retail Marijuana Product is placed for sale to a consumer and that has been labeled according to the requirements set forth in Rules R 1002 *et. seq.* 

"Critical Fluid Extraction Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by extracting cannbiniods from Retail Marijuana through the use of a hydro-carbon solvent, such as butane or propane, or CO2.

"Denied Applicant" means any Person whose application for licensure pursuant to the Retail Code has been denied.

"Department" means the Colorado Department of Revenue.

"Director" means the Director of the Marijuana Enforcement Division.

"Division" means the Marijuana Enforcement Division.

"Edible Retail Marijuana Product" means any Retail Marijuana Product which is intended to be consumed orally, including but not limited to, any type of food, drink, or pill.

"Executive Director" means the Executive Director of the Department of Revenue.

"Exit Package" means a sealed Container or package provided at the retail point of sale, in which any Retail Marijuana or Retail Marijuana Product already within a Container are placed.

"Fat-Based Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by extracting cannabinoids from Retail Marijuana through the use of butter, olive oil or other typical cooking fats as a solvent.

"Final Agency Order" means an Order of the State Licensing Authority issued in accordance with the Retail Code and the State Administrative Procedure Act. The State Licensing Authority will issue a Final Agency Order following review of the Initial Decision and any exceptions filed thereto or at the conclusion of the declaratory order process. A Final Agency Order is subject to judicial review.

"Flower" means the gametophytic or reproductive state of *Cannabis* in which the plant in in a light cycle intended to produce flowers, trichromes, and cannabinoids characteristic of marijuana.

"Good Cause" for purposes of denial of an initial, renewal, or reinstatement of a license application, means:

- a. The Licensee or Applicant has violated, does not meet, or has failed to comply with any of the terms, conditions, or provisions of the Retail Code, any rules promulgated pursuant to it, or any supplemental relevant state or local law, rule, or regulation;
- b. The Licensee or Applicant has failed to comply with any special terms or conditions that were placed upon the license pursuant to an order of the State Licensing Authority or the relevant local jurisdiction; or
- c. The Licensee's Licensed Premises have been operated in a manner that adversely affects the public health or welfare or the safety of the immediate neighborhood in which the establishment is located.

"Good Moral Character" means an individual with a personal history demonstrating honesty, fairness, and respect for the rights of others and for the law.

"Harvest Batch" means a specifically identified quantity of processed Retail Marijuana that is uniform in strain, cultivated utilizing the same herbicides, pesticides, and fungicides, and harvested at the same time.

"Identity Statement" means the name of the business as it is commonly known and used in any Advertising.

"Immature plant" means a nonflowering Retail Marijuana or Medical Marijuana plant that is no taller than eight inches and no wider than eight inches produced from a cutting, clipping, or seedling and that is in a growing/cultivating container that is no larger than two inches wide and two inches tall that is sealed on the sides and bottom.

"Initial Decision" means a decision of a hearing officer in the Department following a licensing, disciplinary, or other administrative hearing. Either party may file exceptions to the Initial Decision. The State Licensing Authority will review the Initial Decision and any exceptions filed thereto, and will issue a Final Agency Order.

"Licensed Premises" means the premises specified in an application for a license pursuant to the Retail Code that are owned or in possession of the Licensee and within which the Licensee is authorized to cultivate, manufacture, distribute, sell, or test Retail Marijuana in accordance with the provisions of the Retail Code and these rules.

"Licensee" means any Person licensed pursuant to the Retail Code or, in the case of an Occupational License Licensee, any individual licensed pursuant to the Retail Code or Medical Code.

"Limited Access Area" means a building, room, or other contiguous area upon the Licensed Premises where Retail Marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under control of the Licensee.

"Limit of Detection" or "LOD" means the lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit (generally 1%).

"Limit of Quantitation" or "LOQ" means the lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

"MITS" means Marijuana Inventory Tracking Solution.

"MITS Trained Administrator" means an Owner or an occupationally licensed employee of a Retail Marijuana Establishment who has attended and successfully completed MITS training and who has completed any additional training required by the Division.

"MITS User" means an Owner or occupationally licensed Retail Marijuana Establishment employee who is granted MITS User account access for the purposes of conducting inventory tracking functions in the MITS system and who has been successfully trained by a MITS Trained Administrator in the proper and lawful use of MITS.

"Medical Code" means the Colorado Medical Marijuana Code found at sections 12-43.3-101 *et. seg.*, C.R.S.

"Medical Marijuana" means "Medical Marijuana" means marijuana that is grown and sold pursuant to the Medical Code and includes seeds and Immature Plants.

"Medical Marijuana Business" means a Medical Marijuana Center, a Medical Marijuana-Infused Product Manufacturing Business, or an Optional Premises Cultivation Operation.

"Medical Marijuana Center" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-402, C.R.S., and sells medical marijuana to registered patients or primary caregivers as defined in Article XVIII, Section 14 of the Colorado Constitution, but is not a primary caregiver.

"Medical Marijuana-Infused Product" means a product infused with Medical Marijuana that is intended for use or consumption other than by smoking, including but not limited to edible product, ointments, and tinctures. Such products shall not be considered a food or drug for purposes of the "Colorado Food and Drug Act," part 4 of Article 5 of Title 25, C.R.S.

"Medical Marijuana-Infused Products Manufacturing Business" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-404, C.R.S.

"Monitoring" means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a Security Alarm System located at a Retail Marijuana Establishment Licensed Premises, for the purpose of summoning a law enforcement officer to the premises during alarm conditions.

"Monitoring Company" means a person in the business of providing security system Monitoring services for the Licensed Premises of a Retail Marijuana Establishment.

"Notice of Denial" means a written statement from the State Licensing Authority, articulating the reasons or basis for denial of a license application.

"Occupational License" means a license granted to an individual by the State Licensing Authority pursuant to section 12-43.3-401 or 12-43.4-401, C.R.S.

"Optional Premises Cultivation Operation" means a Person licensed pursuant to the Medical Code to operate a business as described in section 12-43.3-403, C.R.S.

"Order to Show Cause" means a document from the State Licensing Authority alleging the grounds for imposing discipline against a Licensee's license.

"Owner" means the Person or Persons whose beneficial interest in the license is such that they bear risk of loss other than as an insurer, have an opportunity to gain profit from the operation or sale of the establishment, and have a controlling interest in a Retail Marijuana Establishment license, and includes any other Person that qualifies as an Owner pursuant to Rule R 204.

"Person" means a natural person, partnership, association, company, corporation, limited liability company, or organization, or a manager, agent, owner, director, servant, officer, or employee thereof; except that "Person" does not include any governmental organization.

"Production Batch" means a group of Retail Marijuana Product created from a production run of marijuana product.

"Proficiency Testing Samples" means performing the same analyses on the same samples and comparing results to ensure the Samples are homogenous and stable, and also that the set of samples analyzed are appropriate to test and display similarities and differences in results.

"Propagation" means the reproduction of Retail Marijuana plants by seeds, cuttings or grafting.

"RFID" means Radio Frequency Identification.

"Respondent" means a Person who has filed a petition for declaratory order that the State Licensing Authority has determined needs a hearing or legal argument or a Licensee who is subject to an Order to Show Cause.

"Restricted Access Area" means a designated and secure area within a Licensed Premises in a Retail Marijuana Store where Retail Marijuana and Retail Marijuana Product are sold, possessed for sale, and displayed for sale, and where no one under the age of 21 is permitted.

"Retail Code" means the Colorado Retail Marijuana Code found at sections 12-43.4-101 et. seq., C.R.S.

"Retail Marijuana" means all parts of the plant of the genus cannabis whether growing or not, the seeds thereof, the resin extracted from any part of the plant, and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or its resin, including marijuana concentrate, that is cultivated, manufactured, distributed, or sold by a licensed Retail Marijuana Establishment. "Retail Marijuana" does not include industrial hemp, nor does it include fiber produced from stalks, oil, or cake made from the seeds of the plant, sterilized seed of the plant

which is incapable of germination, or the weight of any other ingredient combined with marijuana to prepare topical or oral administrations, food, drink, or other product.

"Retail Marijuana Concentrate" means specific subset of Retail Marijuana that was produced by extracting cannabinoids from Retail Marijuana. Types of Retail Marijuana Concentrates include Water-Based Retail Marijuana Concentrates, Solvent-Based Retail Marijuana Concentrates, Critical Fluid Extraction Retail Marijuana Concentrates and Fat-Based Retail Marijuana Concentrates.

"Retail Marijuana Cultivation Facility" means an entity licensed to cultivate, prepare, and package Retail Marijuana and sell Retail Marijuana to Retail Marijuana Establishments, but not to consumers.

"Retail Marijuana Establishment" means a Retail Marijuana Store, a Retail Marijuana Cultivation Facility, a Retail Marijuana Products Manufacturing Facility, or a Retail Marijuana Testing Facility.

"Retail Marijuana Product" means concentrated Retail Marijuana and Retail Marijuana Product that are comprised of Retail Marijuana and other ingredients and are intended for use or consumption, such as, but not limited to, edible product, ointments, and tinctures.

"Retail Marijuana Products Manufacturing Facility" means an entity licensed to purchase Retail Marijuana; manufacture, prepare, and package Retail Marijuana Product; and sell Retail Marijuana and Retail Marijuana Product only to other Retail Marijuana Products Manufacturing Facilities and Retail Marijuana Stores.

"Retail Marijuana Store" means an entity licensed to purchase Retail Marijuana from a Retail Marijuana Cultivation Facility and to purchase Retail Marijuana Product from a Retail Marijuana Products Manufacturing Facility and to sell Retail Marijuana and Retail Marijuana Product to consumers.

"Retail Marijuana Testing Facility" means an entity licensed and certified to analyze and certify the safety and potency of Retail Marijuana.

"Sample" means any Retail Marijuana, Retail Marijuana Product, Medical Marijuana, or Medical Marijuana-Infused Product provided for testing or research purposes to a Retail Marijuana Testing Facility by a Retail Marijuana Establishment or Medical Marijuana Business.

"Security Alarm System" means a device or series of devices, intended to summon law enforcement personnel during, or as a result of, an alarm condition. Devices may include hardwired systems and systems interconnected with a radio frequency method such as cellular or private radio signals that emit or transmit a remote or local audible, visual, or electronic signal; motion detectors, pressure switches, duress alarms (a silent system signal generated by the entry of a designated code into the arming station to indicate that the user is disarming under duress); panic alarms (an audible system signal to indicate an emergency situation); and hold-up alarms (a silent system signal to indicate that a robbery is in progress).

"Shipping Container" means any container or wrapping used solely for the transport of Retail Marijuana or Retail Marijuana Product in bulk, or in a quantity for other Retail Marijuana Establishments.

"Solvent-Based Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by extracting cannbiniods from Retail Marijuana through the use of glycerin, isopropylalcohol, ethanol, or propylene glycol as a solvent.

"Standardized Graphic Symbol" means a graphic image or small design adopted by a Licensee to identify its business.

"State Licensing Authority" means the authority created for the purpose of regulating and controlling the licensing of the cultivation, manufacture, distribution, and sale of Medical Marijuana and Retail Marijuana in Colorado, pursuant to section 12-43.3-201, C.R.S.

"THC" means tetrahydrocannabinol.

"THCA" means tetrahydrocannabinolic acid.

"Universal Symbol" means the image established by the Division and made available to Licensees through the Division's website indicating Retail Marijuana or a Retail Marijuana Product is within a Container.

"Unrecognizable" means marijuana or *Cannabis* plant material rendered indistinguishable from any other plant material.

"Vegetation" means the sporophytic state of the *Cannabis* plant that is a form of asexual reproduction in plants during which plants do not produce resin or flowers and are bulking up to a desired production size for Flowering.

"Water-Based Retail Marijuana Concentrate" means a Retail Marijuana Concentrate that was produced by extracting cannabinoids from Retail Marijuana through the use of only water or ice.

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b) and 12-43.4-202(3)(a)(VIII), C.R.S. Authority also exists in the Colorado Constitution at Article XVIII, Subsection 16(5)(a)(VII). The purpose of this rule is to establish minimum health and safety regulation for Retail Marijuana Cultivation Facilities

#### R 504 – Retail Marijuana Cultivation Facility: Health and Safety Regulations

- A. <u>Local Safety Inspections</u>. A Retail Marijuana Cultivation Facility may be subject to inspection of its Licensed Premises by the local fire department, building inspector, or code enforcement officer to confirm that no health or safety concerns are present. The inspection could result in additional specific standards to meet local jurisdiction restrictions related to Retail Marijuana. An annual fire safety inspection may result in the required installation of fire suppression devices, or other means necessary for adequate fire safety.
- B. <u>General Sanitary Requirements</u>. A Retail Marijuana Cultivation Facility shall take all reasonable measures and precautions to ensure the following:
  - That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with Retail Marijuana shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;
  - 2. That all persons working in direct contact with Retail Marijuana shall conform to hygienic practices while on duty, including but not limited to:
    - a. Maintaining adequate personal cleanliness;
    - b. Washing hands thoroughly in an adequate hand-washing area(s) before starting work and at any other time when the hands may have become soiled or contaminated:
    - c. Hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Licensed Premises and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices; and
    - d. Refraining from having direct contact with Retail Marijuana if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
  - 3. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Retail Marijuana is exposed;

- 4. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
- 5. That there is adequate lighting in all areas where Retail Marijuana are stored or sold, and where equipment or utensils are cleaned;
- That the Licensee provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
- 7. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- 8. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Retail Marijuana concentrates, and pesticide chemicals shall be identified, held, and stored in a manner that protects against contamination of Retail Marijuana, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation, or ordinance;
- 9. That all contact surfaces, including utensils and equipment used for the preparation of Retail Marijuana or Retail Marijuana Product, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained. Only sanitizing agents registered with the Environmental Protection Agency shall be used in a Retail Marijuana Products Manufacturing Facility and used in accordance with labeled instructions:
- 10. That the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the facility's needs;
- 11. That plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the plant and that shall properly convey sewage and liquid disposable waste from the facility. There shall be no cross-connections between the potable and waste water lines;
- 12. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Retail Marijuana or Retail Marijuana Product shall be conducted in accordance with adequate sanitation principles;
- That each Retail Marijuana Cultivation Facility shall provide its employees with adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair; and
- 14. That Retail Marijuana that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms.

- C. <u>Sanitary Requirements for Concentrate Production</u>. If a Retail Marijuana Cultivation Facility produces Retail Marijuana concentrates, all areas in which those concentrates are produced shall be subject to all of sanitary requirements for a Retail Marijuana Manufacturing Facility. *See* Rule R 605 Sanitary Requirements.
- D. <u>Prohibited Chemicals</u>. The following chemicals shall not be used in Retail Marijuana cultivation. Possession of chemicals and/or containers from these chemicals upon the Licensed Premises shall be a violation of this rule. Prohibited chemicals are:

**Chemical Name** 

CAS Registry Number (or EDF Substance ID)

**ALDRIN** 

309-00-2

ARSENIC OXIDE (3)

1327-53-3

ASBESTOS (FRIABLE)

1332-21-4

**AZODRIN** 

6923-22-4

1,4-BENZOQUINONE, 2,3,5,6-TETRACHLORO-

118-75-2

**BINAPACRYL** 

485-31-4

2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL

126-15-8

**BROMOXYNIL BUTYRATE** 

EDF-186

**CADMIUM COMPOUNDS** 

**CAE750** 

CALCIUM ARSENATE [2ASH3O4.2CA]

7778-44-1

**CAMPHECHLOR** 

8001-35-2

**CAPTAFOL** 

2425-06-1

**CARBOFURAN** 

1563-66-2

## **CARBON TETRACHLORIDE** 56-23-5 **CHLORDANE** 57-74-9 CHLORDECONE (KEPONE) 143-50-0 **CHLORDIMEFORM** 6164-98-3 **CHLOROBENZILATE** 510-15-6 <u>CHLOROMETHOXYPROPYLMERCURIC</u> **ACETATE** [CPMA] EDF-183 **COPPER ARSENATE** 10103-61-4 2,4-D, ISOOCTYL ESTER 25168-26-7 **DAMINOZIDE** 1596-84-5 DDD 72-54-8 DDT 50-29-3 DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS] EDF-187 1,2-DIBROMO-3-CHLOROPROPANE (DBCP) 96-12-8 1,2-DIBROMOETHANE 106-93-4 **1,2-DICHLOROETHANE** 107-06-2 **DIELDRIN** 60-57-1 4,6-DINITRO-O-CRESOL 534-52-1 **DINITROBUTYL PHENOL**

88-85-7 **ENDRIN** 72-20-8 **EPN** 2104-64-5 **ETHYLENE OXIDE** 75-21-8 **FLUOROACETAMIDE** 640-19-7 **GAMMA-LINDANE** 58-89-9 **HEPTACHLOR** 76-44-8 HEXACHLOROBENZENE 118-74-1 1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (MIXTURE OF ISOMERS) 608-73-1 1,3-HEXANEDIOL, 2-ETHYL-94-96-2 **LEAD ARSENATE** 7784-40-9 **LEPTOPHOS** 21609-90-5 **MERCURY** 7439-97-6 **METHAMIDOPHOS** 10265-92-6 **METHYL PARATHION** 298-00-0 **MEVINPHOS** 7786-34-7 **MIREX** 2385-85-5 **NITROFEN** 1836-75-5

# **OCTAMETHYLDIPHOSPHORAMIDE** 152-16-9 **PARATHION** 56-38-2 **PENTACHLOROPHENOL** 87-86-5 PHENYLMERCURIC OLEATE [PMO] EDF-185 **PHOSPHAMIDON** 13171-21-6 **PYRIMINIL** 53558-25-1 **SAFROLE** 94-59-7 **SODIUM ARSENATE** 13464-38-5 **SODIUM ARSENITE** 7784-46-5 2,4,5-T 93-76-5 TERPENE POLYCHLORINATES (STROBANE6) 8001-50-1 THALLIUM(I) SULFATE 7446-18-6 2,4,5-TP ACID (SILVEX) 93-72-1 TRIBUTYLTIN COMPOUNDS EDF-184

2,4,5-TRICHLOROPHENOL 95-95-4

**VINYL CHLORIDE** 

75-01-4

E. The use of Dimethylsulfoxide ("DMSO") in the production of Retail Marijuana shall be prohibited and possession of DMSO upon the Licensed Premises is prohibited.

- F. That all sanitary requirements shall also apply to any Occupational Licensee making a Retail Marijuana concentrate on the Licensed Premises.
- G. Retail Marijuana Cultivation Facilities may only produce water based Retail Marijuana concentrates on its Licensed Premises and only in an area so designated clearly on the current diagram of the Licensed Premises. See Rule R 901- Business Records Required. A Retail Marijuana Cultivation Facility is prohibited from engaging in any other method of extraction.

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b), C.R.S. The purpose of this rule is to establish the types of Retail Marijuana Concentrates that may be produced at a Retail Marijuana Cultivation Facility and standards for the production of those concentrates.

#### R 506 – Retail Marijuana Cultivation Facilities: Retail Marijuana Concentrate Production

- A. Permissible Types of Concentrate Production. A Retail Marijuana Cultivation Facility may only produce Water-Based Retail Marijuana Concentrates on its Licensed Premises and only in an area clearly designated for concentrate production on the current diagram of the Licensed Premises. See Rule R 901- Business Records Required. No other method of production or extraction for Retail Marijuana Concentrates may be conducted within the Licensed Premise of a Retail Marijuana Cultivation Facility.
- B. <u>Safety and Sanitary Requirements for Concentrate Production</u>. If a Retail Marijuana Cultivation Facility produces Water-Based Retail Marijuana Concentrates, all areas in which those concentrates are produced and all Owners and Occupational Licensees engaged in the production of those concentrates shall be subject to all of requirements imposed upon a Retail Marijuana Products Manufacturing Facility that produces Water-Based Retail Marijuana Concentrates. *See* Rule R 605 Sanitary Requirements and Rule R 606 Concentrate Production.

The statutory authority for this rule is found at subsections 12-43.4-202(2)(b). The purpose of this rule is to establish the types of Retail Marijuana Concentrates that may be produced at a Retail Marijuana Products Manufacturing Facility and establish standards for the production of those concentrates.

#### R 605 – Retail Marijuana Products Manufacturing Facility: Retail Marijuana Concentrate Production

### A. Permissible Types of Concentrate Production.

- 1. A Retail Marijuana Products Manufacturing Facility may produce Water-Based Retail Marijuana Concentrates, Fat-Based Retail Marijuana Concentrates and Solvent-Based Retail Marijuana Concentrate. A Retail Marijuana Products Manufacturing Facility may also produce Critical Fluid Extraction Retail Marijuana Concentrates, provided the VOC solvents used in the process only include: N-Butane, Iso-Butane, Propane, Heptane, or CO2. The use of any other solvent is expressly prohibited unless and until it is approved by the Division.
- 2. A Retail Marijuana Products Manufacturing Facility may apply to the Division for approval of additional types of solvents or production methods.
- B. <u>General Applicability</u>. A Retail Marijuana Products Manufacturing Facility that engages in the production of Retail Marijuana Concentrates, regardless of the method of extraction or type of concentrate being produced, must:
  - 1. Ensure that the space in which any Retail Marijuana Concentrate is to be produced is a fully enclosed room and clearly designated on the current diagram of the Licensed Premises. See Rule M 901- Business Records Required.
  - 2. Establish a standard operating procedure for each method used to produce a Retail Marijuana Concentrate on its Licensed Premise.
  - 3. Establish written and documentable quality control procedures designed to minimize any potential risks to employees or contamination of products.
  - 4. Have a comprehensive training manual that provides step-by-step instructions for each method used to produce a Retail Marijuana Concentrate on its Licensed Premise. The training manual must include, but need not be limited to, all standard operating procedures, quality control procedures and safety procedures for each method of production, instructions on the appropriate use and maintenance of all equipment involved in each process, and any cleaning required to comply with all applicable sanitary rules.
  - 5. Provide adequate training to every Owner or Occupational Licensee prior that to individual engaging the production of a Retail Marijuana Concentrate. Adequate training must include, but need not be limited to, providing the Owner or Occupational Licensee with the training manual for that Licensed Premise and live, in-person instruction detailing safety procedures for each method of production, instructions on the appropriate use and maintenance of all equipment involved in the process, and any cleaning required to maintain compliance with all applicable sanitary rules.

- 6. Maintain clear and comprehensive records that document every phase of each Production Run of Retail Marijuana Concentrate, which must include the name and license number of every Owner or Occupational Licensee that worked on the production of that Retail Marijuana Concentrate.
- C. Water-Based Retail Marijuana Concentrates, Fat-Based Retail Marijuana Concentrates and Solvent-Based Retail Marijuana Concentrates. A Retail Marijuana Products Manufacturing Facility that engages in the production of a Water-Based Retail Marijuana Concentrate, a Fat-Based Retail Marijuana Concentrate, or a Solvent-Based Retail Marijuana Concentrate must:
  - Establish a standard operating procedure for each type of Water-Based Retail Marijuana Concentrate, a Fat-Based Retail Marijuana Concentrate, or a Solvent-Based Retail Marijuana Concentrate to be produced at that Licensed Premise that is designed to minimize the potential for the development of microbials and mold and presence of residual solvents (when necessary).
  - Require each Owner or Occupational Licensee to thoroughly wash his or her hands prior to engaging in any activity related to the production of a Water-Based Retail Marijuana Concentrate, a Fat-Based Retail Marijuana Concentrate, or a Solvent-Based Retail Marijuana Concentrate.
  - 3. Ensure that all equipment used in the production of a Water-Based Retail Marijuana Concentrate, a Fat-Based Retail Marijuana Concentrate, or a Solvent-Based Retail Marijuana Concentrate is food-grade, including ensuring that all counters and surface areas were constructed in such a manner that it reduces the potential for the development of microbials and mold and can be easily cleaned.
  - 4. Ensure that all equipment, counters, and surfaces used in the production of a Water-Based Retail Marijuana Concentrate, a Fat-Based Retail Marijuana Concentrate, or a Solvent-Based Retail Marijuana Concentrate is thoroughly cleaned after the completion of each Production Batch.
- D. <u>Critical Fluid Extraction Retail Marijuana Concentrates</u>. A Retail Marijuana Products Manufacturing Facility that engages in the production of Critical Fluid Extraction Retail Marijuana Concentrates must:
  - 1. Ensure that the facility and all equipment used in production of the Critical Fluid Extraction Retail Marijuana Concentrate meets the following requirements:
    - A professional grade, closed-loop extraction system capable of recovering the solvent used;
    - b. If a pressurized extraction system is utilized, then every vessel in the system must be rated to a minimum of nine hundred pounds per square inch;
    - c. A sufficient fume hood and exhaust system is installed in the room in which a Critical Fluid Extraction Retail Marijuana Concentrate shall be produced and that the system is fully functioning prior to the production a Critical Fluid Extraction Retail Marijuana Concentrate;

- d. All flammable material used in the production of a Critical Fluid Extraction Retail Marijuana Concentrate are stored in a storage-tank designed to hold flammable material and is outside of the room in which the concentrates are to be produced;
- A sufficient fire-suppression system is installed in the room in which a Critical Fluid Extraction Retail Marijuana Concentrate shall be produced and that the system is fully functioning prior to the production a Critical Fluid Extraction Retail Marijuana Concentrate;
- f. All equipment used in the production of a Critical Fluid Extraction Retail Marijuana Concentrate is food-grade and all counters and surface areas are constructed in such a manner that it reduces the potential for the development of microbials and mold and can be easily cleaned;
- g. A hydro-carbon gas monitoring system, a CO2 Gas monitoring system or both, depending on the type of Retail Marijuana Concentrate to be produced, with emergency shutdown relays is installed in the room in which a Critical Fluid Extraction Retail Marijuana Concentrate shall be produced and that the system is fully functioning prior to the production a Critical Fluid Extraction Retail Marijuana Concentrate;
- h. The room in which a Critical Fluid Extraction Retail Marijuana Concentrate shall be produced is a spark-free environment, which shall include the use of NEC Class 1 Division 2 outlets, lights and junction boxes, the grounding of all outlets and the placement of grounding mats along the floor and on work surfaces. This requirement shall not apply to a Retail Marijuana Products Manufacturing Facility that only uses CO2 to produce Critical Fluid Extraction Retail Marijuana Concentrate and
- i. The room in which a Critical Fluid Extraction Retail Marijuana Concentrate shall be produced contains an emergency shower. This requirement shall not apply to a Retail Marijuana Products Manufacturing Facility that only uses CO2 to produce Critical Fluid Extraction Retail Marijuana Concentrate.
- 2. Ensure that all fluids used in the extraction process are food-grade and 99% pure by obtaining a Material Safety Data Sheet from the fluids manufacturer or distributor. A Retail Marijuana Products Manufacturing Facility must maintain a copy of the Material Safety Data Sheet and a receipt of purchase for all fluids used or to be used in an extraction process.
- Establish a standard operating procedure for each type of Critical Fluid Extraction Retail
  Marijuana Concentrate to be produced at that Licensed Premise that is designed to
  maximize employee safety and minimize potential contamination of products with residual
  solvents or microbials and mold.
- 4. Require each Owner or Occupational Licensee to thoroughly wash his or her hands prior to engaging in any activity related to the production of a Critical Fluid Extraction Retail Marijuana Concentrate.

5. Obtain a report from an industrial hygienist certified by the American Board of Industrial Hygiene and Professional Engineer that verifies that the facility and standard operating procedures comply with all applicable local and state laws and adequately protect the facility and persons within the facility and adjacent properties from harm.